K003804

AUG 3 0 2001

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Maersk Medical A/S
Niko Business Unit
Engmosen 1
DK-3540, Lynge
Denmark
Phone No.: 011 45 48 16 70 30

Contact Person: Mr. Christian Pelch

Date of Preparation: December 6, 2000

II. DEVICE NAME

Proprietary Name: Sensi - Prema Neonatal ECG Electrodes
Common Name: ECG Electrode
Classification Name: Electrocardiograph Electrode

III. PREDICATE DEVICES

Blue Sensor Supatab Disposable Electrodes, Medicotest A/S, K983689
Arbo H85V/H87V/H27V Disposable Monitoring Electrodes, Arbo Medical, Inc., K935437

IV. DEVICE DESCRIPTION

Sensi-Prema neonatal ECG electrodes are 22 or 30 mm in diameter and consist of a conductive adhesive hydrogel, a Ag/AgCl plated sensor element, a polyester substrate and vinyl label, and a 12 cm or 60 cm flexible tinned copper or carbon fiber (radiotranslucent) lead wire terminating in a 1.5 mm, 2 mm, or 4 mm standard DIN connector. Electrodes are packaged in pouches of 3, 100 pouches per carton and are supplied non-sterile.

V. INTENDED USE

ECG monitoring electrodes for short-term use (<24 hours) in neonates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Niko Medical Products
c/o Mr. Richard A. Hamer
Richard Hamer Associates, Inc.
6401 Meadows West
Forth Worth, TX 76132

Re: K003804
Trade Name: Sensi-Prema Neonatal ECG Electrodes
Regulation Number: 21 CFR 870.2360
Regulatory Class: II (two)
Product Code: DRX
Dated: May 31, 2001
Received: June 4, 2001

Dear Mr. Hamer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003804

Device Name: Sensi - Prema Neonatal ECG Electrodes

Indications for Use:

ECG monitoring electrodes for short-term use (< 24 hours) in neonates.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003804

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)